



## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

[Docket No. DEA-392]

#### Manufacturer of Controlled Substances Registration: Cambrex Charles City

**ACTION:** Notice of registration.

**SUMMARY:** Cambrex Charles City applied to be registered as a manufacturer of certain basic classes of controlled substances. The Drug Enforcement Administration (DEA) grants Cambrex Charles City registration as a manufacturer of those controlled substances.

#### SUPPLEMENTARY INFORMATION:

By notice dated October 13, 2015, and published in the *Federal Register* on October 21, 2015, 80 FR 63835, Cambrex Charles City, 1205 11<sup>th</sup> Street, Charles City, Iowa 50616 applied to be registered as a manufacturer of certain basic classes of controlled substances. No other comments or objections were submitted for this notice.

The DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of Cambrex Charles City to manufacture the basic classes of controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated the company's maintenance of effective controls against diversion by inspecting and testing the company's physical security systems, verifying the company's compliance with state and local laws, and reviewing the company's background and history.

Therefore, pursuant to 21 U.S.C. 823(a), and in accordance with 21 CFR 1301.33, the above-named company is granted registration as a bulk manufacturer of the following basic classes of controlled substances:

<b><u>Controlled Substance</u></b>	<b><u>Schedule</u></b>
Amphetamine (1100)	II
Lisdexamfetamine (1205)	II
Methylphenidate (1724)	II
4-Anilino-N-phenethyl-4-piperidine (ANPP) (8333)	II
Phenylacetone (8501)	II
Cocaine (9041)	II
Codeine (9050)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Hydrocodone (9193)	II
Morphine (9300)	II
Oripavine (9330)	II
Thebaine (9333)	II
Opium extracts (9610)	II
Opium fluid extract (9620)	II
Opium tincture (9630)	II
Opium, powdered (9639)	II
Oxymorphone (9652)	II
Noroxymorphone (9668)	II
Fentanyl (9801)	II

The company plans to manufacture the listed controlled substances in bulk for sale to its customers, for dosage form development, for clinical trials, and for use in stability qualification studies.

Dated: March 14, 2016.

Louis J. Milione,  
*Deputy Assistant Administrator.*